DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 28 1999

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Re: Tisseel VH Kit®
Docket No. 98E-0791

The Honorable Q. Todd Dickinson
Deputy Assistant Commissioner for
Patent Policy and Projects
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, DC 20231

Dear Commissioner Dickinson:

This is in regard to the patent term extension application for U.S. Patent No. 4,362,567 filed by Immuno Aktiengesellschaft fur chemsih-medizinshe Produkte under 35 U.S.C. § 156. The patent claims the human biological product Tisseel VH Kit®, product license application PLA 87-0509.

In the November 25, 1998, issue of the Federal Register (63 Fed. Reg. 65211), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before May 24, 1999, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: John L. Isacson
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